

REMARKS

Reconsideration of the above-identified application in view of the above amendments and following remarks is respectfully requested. Claims 172, 179-185, 189-190, 192, 194, 202, 204, 206 and 209 have been amended. Claims 178 and 213-220 have been cancelled. Claims 172-177 and 179-212 are now pending.

Amendment of Claims 172, 179-185, 189-190, 192, 194, 202, 204, 206 and 209

Applicants have amended claim 172 to include the element previously set forth in claim 178, namely, a resuspension pump interface in fluidic connection with the sample storage channel and positioned downstream of the sample inlet. Accordingly, previously pending claim 178 has been cancelled and the dependencies of claims 179-181 have been corrected. In addition, Applicants have made a number of minor clarifying amendments to claims 172, 182-185, 189-190, 192, 194, 202, 204, 206 and 209. Applicants submit that the such amendments do not constitute the addition of new matter.

Cancellation of Claims 213-220

In order expedite allowance of claims 172-177 and 179-212, Applicants have cancelled claims 213-220 without prejudice to the filing of any divisional, continuation, or continuation-in-part application.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 172-220 stand rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not reasonably provide enablement for a “nonporous” sample storage channel. Although Applicants respectively disagree with the Examiner’s conclusion, in order to expedite allowance of pending claims 172-177 and 179-212, Applicants have deleted the term “non-porous”. Accordingly, Applicants request that this ground of rejection be withdrawn.

Rejection Under 35 U.S.C. § 102(b)

Claims 172-180, 182-183, 185-188, 195-198, 201, 203-208, 210-214, 217, 219-220 stand rejected under 35 U.S.C. § 102(b) as anticipated by Kaltenbach et al. (WO 96/12546). Applicants respectfully disagree with several of the Examiner's conclusions set forth below and submit that Kaltenbach does not disclose every element of amended claim 172.

As stated by the Examiner, Kaltenbach discloses a sample analysis cartridge 2, 52 comprising a sample inlet 22 and a storage channel 10 having a plurality of particle capture regions (shown in the embodiment illustrated in FIG. 1 of Kaltenbach). The Examiner further states that Kaltenbach discloses the sample inlet having an inlet shut-off interface (see page 21 of Kaltenbach) and the sample analysis cartridge comprising a first analysis region in fluidic connection with the storage channel and an analysis valve 106 positioned between the storage channel and the first analysis region. In addition, the Examiner states that Kaltenbach discloses a reagent inlet 34 connected to a reagent reservoir compartment 16, 68 and a resuspension pump (see page 23-24 of Kaltenbach) for displacing fluid from the reservoir into a mixing channel 72 between the reservoir and the first analysis region.

As set forth above, claim 172, as amended, is directed to a sample analysis cartridge comprising: (1) a sample inlet comprising an inlet shut-off interface; (2) a convoluted sample storage channel in fluidic connection with the sample inlet, wherein the storage channel comprises a plurality of particle capture regions; (3) a resuspension pump interface, in fluidic connection with the storage channel and positioned downstream of the sample inlet; (4) a first analysis channel in fluidic connection with the storage channel, the first analysis channel comprising a first analysis region; and (5) a first analysis valve interface positioned between the storage channel and the first analysis channel.

Applicants submit that the Kaltenbach does not disclose a sample analysis cartridge comprising all of the foregoing elements. In particular, Kaltenbach does not disclose a sample inlet, resuspension pump interface or first analysis valve as claimed by the present invention.

1. Claim 172, as amended, recites, *inter alia*, "a sample inlet comprising an inlet shut-off interface". As described in the present application at page 7, lines 4-7, an

integrated inlet shut-off interface, such as a septum or integrated valve interface, is employed to prevent a loaded sample from leaking out of the disclosed analysis cartridge. Kaltenbach does not disclose the use of such an *integrated* shut-off interface. Contrary to the Examiner's conclusion, the cited paragraphs on page 21 of Kaltenbach describe the use of *external* valving and injection means to introduce a fluid into reagent inlet 34 (which is connected to reagent reservoir compartment 16, 68). Such paragraphs neither disclose the use of integrated shut-off interface components nor disclose the use of such components for the introduction of a fluid into sample inlet 22 (which is connected to storage channel 10).

2. Claim 172, as amended, recites, *inter alia*, "a resuspension pump interface in fluidic connection with said storage channel and positioned downstream of said sample inlet". As described in the present application at page 7, lines 10-11, such an integrated resuspension pump interface is used for reconstituting a sedimentated sample following stop flow or storage. Kaltenbach does not disclose the use of such a resuspension pump interface in fluidic connection with the storage channel disclosed therein. Applicants note that the resuspension pump (*i.e.*, optional actuator means 102) disclosed in Kaltenbach, and referenced by the Examiner, is disposed over reservoir compartment 16, 68, not the storage channel, and is employed to displace fluid from the reservoir into a mixing channel 72 between the reservoir and the first analysis region.

3. Claim 172, as amended, recites, *inter alia*, "a first analysis valve interface positioned between said storage channel and said first analysis channel." Contrary to the Examiner's conclusion, Kaltenbach does not disclose a first analysis valve interface between a storage channel and first analysis channel. According to the Examiner's interpretation, the storage channel 10 disclosed in Kaltenbach comprises a storage region and an analysis region, corresponding to the storage channel and first analysis channel, respectively, of the present invention (see modified FIG. 3 on page 3 of the present office action). The Examiner points to microvalve 106 (disclosed in FIG. 5 and the corresponding description at page 24, lines 3-13) as being positioned between such storage and analysis regions, however, as shown in FIG. 5, microvalve 106 is positioned between the analysis region and the reservoir compartment 16, 68, rather than the storage channel as in the analysis cartridge of the present invention.

In view of the foregoing, Applicants respectfully submit that Kaltenbach does not disclose every element of amended claim 172. Furthermore, Applicants submit that there is no teaching or suggestion in Kaltenbach to modify the sample analysis cartridge disclosed therein in order to produce the claimed sample analysis cartridge of the present invention. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 181, 184, 199-200, 202, 215 stand rejected under 35 U.S.C. § 103(a) as obvious over Kaltenbach. Claims 189-194 and 209 stand rejected under 35 U.S.C. § 103(a) as obvious Kaltenbach in view of Altendorf et al. (U.S. Patent No. 5,726,751). Claim 216 stands rejected under 35 U.S.C. § 103(a) as obvious over Kaltenbach in view of Miyake et al. (U.S. Patent No. 5,736,100). Claim 218 stands rejected under 35 U.S.C. § 103(a) as obvious over Kaltenbach in view of Zanzucchi et al. (U.S. Patent No. 5,755,942).

All of the foregoing rejections are based on the Examiner's conclusion that Kaltenbach discloses the sample analysis cartridge of claim 172. However, as set forth above, Kaltenbach does not disclose the sample analysis cartridge of amended claim 172. Furthermore, none of the foregoing references, namely, Kaltenbach, Altendorf, Miyake and Zanzucchi, contain any teaching or suggestion to modify the devices disclosed therein in order to produce the claimed sample analysis cartridge of the present invention. Accordingly, Applicants request that these grounds of rejection be withdrawn.

In view of the above amendment and remarks, allowance of claims 172-177 and 179-212 is respectfully requested. A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at (206) 622-4900 to resolve the same. Furthermore, the Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

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